

Serial No. 09/868,974

Remarks

In this response, Applicants have amended Claims 34 to be more clear.

REJECTION UNDER 35 U.S.C. § 102(e)/ § 103

Applicants respectfully maintain the position that the Hoffmann reference (U.S. Patent No. 6,358,924) is not a 102 or a 103 reference. Section 103 (c) prevents a potential 102 (e) reference from being prior art for 103 purposes if the prior art subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. 35 U.S.C. 103(c)(1).

In this case the prior art subject matter and the claimed invention were subject to an obligation of assignment to Eli Lilly and Company at the time the invention was made. Applicants therefore, request reconsideration and withdrawal of this rejection.

In the event the Examiner is using the Hoffmann reference as a 102 (e) reference for anticipation purposes, Applicants respectfully request Examiner withdraw this rejection as not every element in Hoffmann is disclosed in Applicants claimed invention. Hoffmann focuses on GLP peptides that bind surfactants with high affinity which are useful for oral absorption and long term storage. The pH range that Hoffmann discloses is specifically from 6.5 to 9.0 and preferably from 7 to 8. (See US 6,358,924, col. 2, lines 12-13). Hoffman discloses in Example 1 that a solution formulation at pH 8.1, in the absence of or in the presence of a small amount of a surfactant, became and remained hazy. (See US 6,358,924, col. 6, lines 60-61).

Applicants claimed invention recites a pH range of 8.2 to 8.8. Therefore, this element is missing in Hoffmann. The MPEP states that when the prior art discloses a range which touches, overlaps or is within the claimed range, but no specific examples falling within the claimed range are disclosed, a case by case determination must be made as to anticipation. In order to anticipate the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute." This is fact dependent. If the claims are directed to a narrow range, the reference teaches a broad range, and there is evidence of unexpected results within the claimed narrow range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with sufficient specificity to constitute an anticipation of the claims. MPEP §2131.03 II.

Applicants have shown that the narrow pH range provides the desired physical stability and chemical stability for the claimed solution formulation. The Specification states:

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One factor that plays a role in the stability of GLP-1 formulations is the maintenance of pH at a prescribed level. Specifically, the present inventors have found that achieving and maintaining the pH of the formulation at about 8.2 to about 8.8 is advantageous. Typical peptide formulations have a more neutral pH of 7 to about 7.8 or an acidic pH. Furthermore, a composition containing a GLP-1 molecule that has a pH in the range of about 6.8 to about 7.5 exhibits less physical stability than a composition of a GLP-1 molecule containing a preservative and having a pH in the range of about 8.2 to about 8.8. A preserved formulation which has a pH of less than about 8.0 tends to exhibit turbidity, a telltale sign of decreased physical stability of the peptide formulation. Conversely, a formulation which has a pH greater than about 8.8 tends to have decreased chemical stability. Therefore, the invention contemplates GLP-1 formulations having a pH range of about 8.2 to about 8.8, which preserves optimal-chemical and physical stability of the GLP-1 molecule. (Page 6, line 28 to page 7, line 9. See also Examples 1 and 2.)

Thus, the described pH range of about 8.2 to about 8.8 provides a stable solution formulation that is not disclosed in Hoffmann and therefore, cannot be anticipated by Hoffmann.

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SUMMARY AND CONCLUSION

Applicants respectfully assert that the application is in condition for allowance. The claims are novel and clear in their meaning.

If, for any reason, the Examiner feels that a telephone conversation would be helpful in expediting the prosecution of this case, the Examiner is urged to call me.

Respectfully submitted,



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